JUN 2 7 2000

K000683

p. 1 of 2

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.

Manufacturer: Biomet Manufacturing, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Proprietary Name: Modified Single Axle Elbow

Common or Usual Name: Elbow Prosthesis

Classification Name: Elbow joint metal/polymer constrained cemented prosthesis

Device Classification: Class III (888.3150) – Class II reclassification pending

Device Product Code: 87JDC

Device Description: The Modified Single Axle Total Elbow system is a product line extension of the previously cleared Single Axle Total Elbow.

The previously cleared humeral component underwent minor changes to produce the standard line humeral components. These minor changes include making the component no longer a patient matched humeral component by creating geometrical dimensions that will match a majority of the patient population. Another change is the addition of a 100% porous coated standard line ulnar component. These changes are simply to accommodate a greater range of patient anatomy thereby creating a stock total elbow prosthesis instead of patient matched components.

The Single Axle Total Elbow ulnar components were previously cleared as patient matched Ti-6Al-4V components. The modified ulnar components are standard line CoCrMo components. These standard line components are made to dimensions that will allow them to be used for wide ranges of patient anatomy.

The modular humeral device consists of three components – humeral stem, modular segment and an assembly screw. The humeral stem and the modular segment are joined by means of a Morse locking taper, additional fixation is achieved with a locking screw.

Indications For Use: The Single Axle Total Elbow is indicated for use in rheumatoid arthritis, non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, correction of severe functional deformity, revision procedures where other treatments or devices have failed, and treatment of acute or chronic fractures with humeral epicondyle involvement which are unmanageable using other treatment methods. This linked constrained elbow prosthesis is indicated for joints with both intact and limited soft tissue structure about the elbow.

This device is a single use implant. It is intended for use with bone cement.

K001078 p 2 of 2

Potential Risks: : The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

Reaction to bone cement	Bone fracture
Fracture of the components	Hematoma
Cardiovascular disorders	Blood vessel damage
Implant loosening/migration	Nerve damage
Soft tissue imbalance	Excessive wear
Deformity of the joint	Infection
Delayed wound healing	Metal sensitivity
Fracture of the cement	Breakdown of porous surface
Dislocation	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 7 2000

Ms. Tina Lakin
Regulatory Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581

Re: K000683
Trade Name: Single Axle Total Elbow
Regulatory Class: III
Product Code: JDC
Dated: June 1, 2000
Received: June 2, 2000

Dear Ms. Lakin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Russell O. Hayes

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known) : K000683

Device Name: Modified Single Axle Total Elbow

Indications For Use: The Modified Single Axle Total Elbow is indicated for use in rheumatoid arthritis, non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis, correction of severe functional deformity, revision procedures where other treatments or devices have failed, and treatment of acute or chronic fractures with humeral epicondyle involvement which are unmanageable using other treatment methods. This linked constrained elbow prosthesis is indicated for joints with both intact and limited soft tissue structure about the elbow.

This device is a single use implant. It is intended for use with bone cement.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000683

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)